

REMARKS

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the following remarks.

Claims 1, 2 and 5-37 are pending in the subject application. Claims 1, 2, 5-6, 7-25, 33, 34-36 stand rejected under 35 U.S.C. §102(b) as being anticipated by Anderson (795). Claims 26-32 and 37 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson (795) in view of Gleason.

Favorable reconsideration in light of the amendments and remarks which follows respectfully requested.

1. 35 U.S.C. §102 Rejections

Claims 1, 2, 5-6, 7-25, 33, 34-36 have been rejected under 35 U.S.C. §102(b) as being anticipated by Anderson (795). The Office states:

Anderson (795) discloses a method and apparatus showing the positioning of the body portion (umbilical cord) within a curved shield member (21) of medical grade material (Co. 4, lns. 51-55), and inserting an insertion member into the umbilical cord to extract blood (Col. 5, lns. 21-67) in the form of a hollow needle (73). The step of stabilizing the body portion with a digit, (Col. 3 at line 10-12) is disclosed. Regarding claim 11, the withdrawal step and the removing the body portion of obvious steps that the physician would take to complete the process.

Applicants respectfully traverse this rejection.

Applicants claim, in claim 1, a method for collection of blood comprising positioning a body portion, from which blood is to be withdrawn, within a shield member such that the shield member is generally disposed between the body portion and a hand of a user; stabilizing the body portion using a digit of the user's hand; and inserting an insertion member of a blood extraction device into the body portion such that the shield member is generally disposed between the insertion member and the user's hand.

Applicants respectfully disagree with the Office's assertion that "The step of stabilizing the body portion with a digit, (Col. 3 at line 10-12) is disclosed" by the Anderson reference. Column 3, lines 10-12 of Anderson reads as follows:

A stem that has first and second ends is operatively connected to the bottom surface of the trough. The stem allows a user to hold and maneuver the umbilical cord holder during use.

The stem is shown in the figures as reference numeral 36. It is a downward extension from the bottom of the trough 21. The trough is curved and has an open top 22 into which the umbilical cord is placed and clamped on each end using clamps 26, 32. Column 3, lines 10-12 merely states that there is a portion called a stem 36 extending from the bottom of the trough 21 that may be held by a user such that the umbilical cord holder can be held during use. Nothing in column 3, lines 10-12 states or even suggests that a body portion from which blood is withdrawn (e.g. umbilical cord) can be stabilized using a digit of the user's hand. Rather, column 3, lines 10-12 and the remainder of the reference suggest just the opposite. The user holds the umbilical cord by the stem 36, which extends from the bottom of the trough 21. The other hand holds the syringe that is used to withdraw blood. If the user holds the stem 36 with one hand as specified, then it would be very difficult and awkward for the user to stabilize the umbilical cord with a digit of the same hand. Doing so would compromise the user's steady hold on the device.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

As set forth above, each and every element of claim 1 is not found expressly in the Anderson reference. The portion of the Anderson reference pointed to by the Office as disclosing the step of stabilizing the body portion with a digit does not disclose this at all. Rather, it merely states that the stem of the holder can be held by a user. Nothing regarding stabilizing the body portion (e.g. umbilical cord) with a digit of the user's hand is mention or even suggested in this portion or any other portion of the Anderson reference. Further, this step is not inherent in the Anderson reference. It is well-established that "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990); MPEP 2112. It is clear that the step of stabilizing the body portion (e.g. umbilical cord) with a digit of the user's hand does not necessarily flow from the teachings of Anderson. Rather, Anderson specifies that the clamps secure and hold the umbilical cord within the trough.

Applicants respectfully submit that the Anderson reference does not describe each and every element as set forth in claim 1. In particular, the Anderson reference does not describe or otherwise suggest stabilizing the body portion (umbilical cord) using a digit of the user's hand. Claims 2, 5-15 and 33 depend from claim 1 and, likewise, are patentable over the Anderson reference. Independent claims 16, 19, 25, 34 and 36 contain similar claim language as in claim 1 and, likewise, are patentable over the Anderson reference. Claims 17-18, 20-24 and 35 depend from claims 16 and 34 and, likewise, are patentable over the Anderson reference.

3. 35 U.S.C. §103 Rejections

Claims 26-32 and 37 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson (795) in view of Gleason. The Office states:

Anderson (795) discloses the limitations above but do not disclose the use of the device with a kit.

Gleason discloses the use of a blood collection/sampling device in a kit in an analogous art for

the purpose of having ready access to all the necessary devices to perform the operation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Anderson (795) as shown by Gleason because the inclusion of the device in a kit would make the device more useful when it would be needed.

Applicants respectfully traverse this rejection for the same reasons as set forth above regarding the Anderson reference. Further, the Gleason reference does not remedy the deficiencies set out above regarding the Anderson reference.

Applicants further submit that claims 1, 2, 5-6, 7-25, 33, 34-36 are not patentable under 35 U.S.C. §103(a) for the reasons provided above. Namely, Anderson does not describe each and every element set out in independent claims 1, 16, 19, 25, 34 or 36.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 2142.

As set out above, Anderson does not describe a method for collection of blood comprising positioning a body portion, from which blood is to be withdrawn, within a shield member such that the shield member is generally disposed between the body portion and a hand of a user and stabilizing the body portion using a digit of the user's hand. Further, the Anderson reference does not suggest such a method. The device described by Anderson clearly was not designed such that the user stabilizes the umbilical cord with a digit of his/her hand. Rather, it was specifically designed with umbilical cord clamps 26, 32 on each end of the trough 21 so that the clamps 26,

32 hold and stabilize the umbilical cord. There is absolutely no teaching or description that one uses a digit of one's hand to stabilize the umbilical cord. Further, there is absolutely no suggestion to do so. Rather, Anderson specifically includes umbilical cord clamps 26, 32 located on opposite ends of the trough 21 such that opposite ends of the umbilical cord can be clamped and the umbilical cord restricted. As specified by Anderson "The umbilical cord holder 20 also maintains the umbilical cord substantially still while the user is inserting the hollow needle 73." (Col. 6, lines 28-30) Thus, it is the umbilical cord holder, with its umbilical cord clamps, that maintains the umbilical cord substantially still -- not a digit of a user's hand as required by Applicants' claim 1.

Still further, Applicants note that in addition to holding the stem 36 in the hand, the user also holds the valve 1 in the same hand. Thus, it would be difficult, if not impossible, for the user to hold the stem and the valve in the same hand and, additionally, to remove one finger of the same hand from the stem and valve and extend it over and around the trough 21 to hold the umbilical cord, while, at the same time, maintaining his/her hold on the stem and valve in the same hand. As set out by Anderson, the device includes a valve system that "allows the operator to remove placental blood and mix it with the appropriate volume and type of anticoagulant and transfer that mixture to an appropriate storage bag all within a closed sterile system and with minimal mechanical motion by the operator" (Col. 2, lines 32-36) This valve is used to distinguish over the Bonn device (U.S. Pat. No. 5,097,842), which the Anderson reference states "does not allow for variability in volume of blood obtained from infant to infant." (Col. 2, lines 32-39)

The arrangement set out by Anderson is critical because, according to Anderson, "The manipulation of the needle must be minimal or the operator will inadvertently withdraw it from the umbilical vessel allowing loss or contamination of the placental blood. The present invention allows the user to manipulate the umbilical cord and secure the needle relevant to the umbilical vein. It also allows the user to hold the umbilical cord and the valve with a single hand. The user's other hand is then free to efficiently withdraw the placental blood, mix it with an anticoagulant, and

store it in a storage bag." (Col. 2, lines 42-51)

Thus, Anderson describes a specific device having specific characteristics as set out above. The device design enables important functions to be carried out. There is absolutely no suggestion or motivation to modify the teachings of Anderson as required by Applicants' claim 1 and, thus, even if the Anderson reference could be modified as set out by Applicants, such a modification not obvious because suggestion to do so is completely lacking. As the Federal circuit has stated, "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992).

Further, it is well-established that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (See MPEP 2143.03)

In this case, all of the claim limitations are not taught or suggested. Thus, the only way to maintain the obviousness rejection would be to impermissibly ignore some of the Applicants' claim limitations.

Accordingly, the above-identified claims are patentable over the Anderson reference. The Gleason reference does not remedy the deficiencies of the Anderson reference and, thus, the above-identified claims are patentable over Anderson in view of Gleason. Reconsideration and withdrawal of the rejections is respectfully requested.

CONCLUSION

Reconsideration and allowance of claims 1, 2 and 5-37 is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for

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immediate allowance. Applicant respectfully requests early consideration and allowance of the subject application.

Applicants believe that no extension of time is required since this response is being filed before the expiration of the specified time period. Applicants, however, conditionally petition for an extension of time to provide for the possibility that such a petition has been inadvertently overlooked and is required. As provided below charge Deposit Account No. **04-1105** for any required fee.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

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Respectfully submitted,

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